

**Experiment Number:** 55312-01  
**Test Type:** 90-DAY  
**Route:** SKIN APPLICATION  
**Species/Strain:** Rat/F 344/N

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)**

**Test Compound:** Coconut oil acid diethanolamine condensate

**CAS Number:** 68603-42-9

**Date Report Requested:** 10/23/2014

**Time Report Requested:** 05:25:39

**First Dose M/F:** NA / NA

**Lab:** BAT

<b>C Number:</b>	C55312B
<b>Lock Date:</b>	09/04/1992
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

Experiment Number: 55312-01

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Date Report Requested: 10/23/2014

Test Type: 90-DAY

Test Compound: Coconut oil acid diethanolamine condensate

Time Report Requested: 05:25:39

Route: SKIN APPLICATION

CAS Number: 68603-42-9

First Dose M/F: NA / NA

Species/Strain: Rat/F 344/N

Lab: BAT

F 344/N Rat MALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
<b>Disposition Summary</b>						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(0)	(0)	(0)	(0)	(10)
Hepatodiaphragmatic Nodule	1 (10%)					1 (10%)
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	6 (60%)					4 (40%)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(6)	(0)	(0)	(0)	(0)	(7)

a - Number of animals examined microscopically at site and number of animals with lesion

Experiment Number: 55312-01

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Date Report Requested: 10/23/2014

Test Type: 90-DAY

Test Compound: Coconut oil acid diethanolamine condensate

Time Report Requested: 05:25:39

Route: SKIN APPLICATION

CAS Number: 68603-42-9

First Dose M/F: NA / NA

Species/Strain: Rat/F 344/N

Lab: BAT

F 344/N Rat MALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	6 (60%)					8 (80%)
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	3 (30%)					3 (30%)
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(1)	(0)	(10)
Germinal Epith, Degeneration				1 (100%)		
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(8)	(0)	(0)	(0)	(0)	(9)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Epidermis, SOA, Hyperplasia		7 (70%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
SOA, Inflammation, Chronic Active				8 (80%)	10 (100%)	10 (100%)
SOA, Parakeratosis				3 (30%)	9 (90%)	10 (100%)
SOA, Sebaceous Gl, Hyperplasia			6 (60%)	9 (90%)	10 (100%)	10 (100%)
SOA, Ulcer				1 (10%)	6 (60%)	7 (70%)
MUSCULOSKELETAL SYSTEM						

a - Number of animals examined microscopically at site and number of animals with lesion

Experiment Number: 55312-01

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: Rat/F 344/N

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)**

Test Compound: Coconut oil acid diethanolamine condensate

CAS Number: 68603-42-9

Date Report Requested: 10/23/2014

Time Report Requested: 05:25:39

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat MALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Metaplasia, Osseous	1 (10%)					
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Suppurative, Acute						1 (10%)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(9)	(9)	(9)	(5)	(10)
Renal Tubule, Regeneration	9 (90%)	9 (100%)	9 (100%)	9 (100%)	5 (100%)	3 (30%)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

\*\*\*END OF MALE DATA\*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion

Experiment Number: 55312-01

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)**

Date Report Requested: 10/23/2014

Test Type: 90-DAY

Test Compound: Coconut oil acid diethanolamine condensate

Time Report Requested: 05:25:39

Route: SKIN APPLICATION

CAS Number: 68603-42-9

First Dose M/F: NA / NA

Species/Strain: Rat/F 344/N

Lab: BAT

F 344/N Rat FEMALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
<b>Disposition Summary</b>						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(1)	(1)	(1)	(2)	(10)
Artery, Dilatation					1 (50%)	
Atrophy					1 (50%)	
Hepatocyte, Hyperplasia					1 (50%)	
Hepatodiaphragmatic Nodule	1 (10%)	1 (100%)	1 (100%)	1 (100%)	1 (50%)	1 (10%)
Inflammation, Chronic Active					1 (50%)	
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Acinus, Atrophy	1 (10%)					
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	1 (10%)					

a - Number of animals examined microscopically at site and number of animals with lesion

Experiment Number: 55312-01

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: Rat/F 344/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Coconut oil acid diethanolamine condensate

CAS Number: 68603-42-9

Date Report Requested: 10/23/2014

Time Report Requested: 05:25:39

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat FEMALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(8)	(0)	(0)	(0)	(0)	(6)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Craniophar Dct, Pars Distalis, Cyst	2 (20%)					
Pars Distalis, Cyst						1 (10%)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	10 (100%)					10 (100%)
Ovary	(10)	(3)	(3)	(2)	(3)	(10)
Bilateral, Periovarn Tiss, Cyst					1 (33%)	
Periovarn Tiss, Cyst	3 (30%)	3 (100%)	3 (100%)	2 (100%)	2 (67%)	1 (10%)
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(1)	(10)
Hyperplasia, Lymphoid					1 (100%)	
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(10)	(10)	(10)	(10)	(10)

a - Number of animals examined microscopically at site and number of animals with lesion

Experiment Number: 55312-01

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: Rat/F 344/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Coconut oil acid diethanolamine condensate

CAS Number: 68603-42-9

Date Report Requested: 10/23/2014

Time Report Requested: 05:25:39

First Dose M/F: NA / NA

Lab: BAT

F 344/N Rat FEMALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
Epidermis, SOA, Hyperplasia		2 (20%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
SOA, Inflammation, Chronic Active				9 (90%)	10 (100%)	10 (100%)
SOA, Parakeratosis					10 (100%)	10 (100%)
SOA, Sebaceous Gl, Hyperplasia				7 (70%)	10 (100%)	10 (100%)
SOA, Ulcer					10 (100%)	10 (100%)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Acute	1 (10%)					
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
None						
<b>URINARY SYSTEM</b>						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Infarct					1 (10%)	
Mineralization	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Renal Tubule, Regeneration	3 (30%)	5 (50%)	7 (70%)	10 (100%)	10 (100%)	10 (100%)
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

\*\* END OF REPORT \*\*